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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,136	08/26/2003	Kendall M. Mohler	2959-B	3243

22932 7590 12/20/2005

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EXAMINER	
HADDAD, MAHER M	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 12/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/648,136	MOHLER ET AL.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *24-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/26/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-28 are pending.

It is noted that the restriction did not include claims 22-23 in elected Group I, however, after further consideration, claims 22-23 should be included in elected Group I.

2. Applicant's election without traverse of Group I, claims 1-21 (now claims 1-23) drawn to a method of treating an autoimmune or chronic inflammatory condition in a patient, wherein agent is an antibody that is specific for CD30L, and the second agent is an antagonist of TNFα and psoriatic arthritis as the species filed on 10/14/05, is acknowledged.

Upon reconsideration the Examiner extend the search to cover all the species.

3. Claims 24-28 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

4. Claims 1-23 are under examination as they read on a method of treating an autoimmune or chronic inflammatory condition in a patient, wherein agent is an antibody that is specific for CD30L, and the second agent is an antagonist of TNFα and psoriatic arthritis, arthritis nodosa, seronegative spondylarthropathies and inflammatory bowel diseases as the species.

5. The specification on page 1 should be amended to reflect the status of parent application No. 09/921,667.

6. It is noted that the parent application No. 09/921,667 has three inventors while the instant application has five inventors. Inventors Jacques J. Peschon and John D. Pluenneke are not inventors in the parent application No. 09/921,667. Clarification is required.

7. Applicant's IDS, filed 8/26/03, is acknowledged.

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1-23 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-5, 6-15, and 22-24 of U.S. Patent No. 6,652,854 in view of U.S. Patent 5,670,527.

The US. `854 patent claims a method of treating multiple sclerosis or rheumatoid arthritis in a patient, said method comprising administering to the patient an agent that comprises an antibody that is specific for CD30L, wherein the agent is administered according to a regimen of dose and frequency of administration that is adequate to induce a sustained improvement in at least one indicator that reflects the severity of the patient's condition, the improvement being considered sustained if the patient exhibits the improvement on at least two occasions separated by at least one day (see patented claim 1 in particular), wherein the patient is a human (see patented claim 2, in particular), wherein the agent is administered concurrently with a second agent that is an antagonist of TNFα, and further wherein the patient's condition is selected form the group consisting of rheumatoid arthritis and SLE (see patented claim 4, in particular), wherein the antibody specific for CD30L is a monoclonal antibody, a humanized antibody or a human antibody (see patented claims 7-9, in particular), wherein the antagonist of TNFα is selected from the group consisting of etanercept, p55 TNFR-Ig fusion protein and an antibody against TNFα (see patented claim 10, in particular), wherein the antagonist of TNFα is an antibody against TNFα, and further wherein said antibody is selected from the group consisting of infliximab, D2E7 and CDP571 (see patented claim 11, in particular), wherein said agent further comprises a physiologically acceptable carrier, excipients and/or diluent (see patented claim 12, in particular).

The claimed invention differs from the claims of US. `854 patent teachings only by the recitation of psoriatic arthritis, seronegative spondylarthropathies, IBD in claim 1, ankylosing spondylitis in claim 3, psoriatic arthritis in claim 4, Cronh's disease or ulcerative colitis in claim 5.

The US. `527 patent teaches compounds that are useful in treatment of disease states caused or exacerbated by excessive or unregulated cytokine production by such mammal's cells such as monocytes and/or macrophases, especially disease states mediated by IL-1, IL-6, IL-8 or TNF, wherein the disease states are rheumatoid arthritis, rheumatoid spondylitis (i.e., ankylosing spondylitis), inflammatory bowel disease, multiple sclerosis, psoriatic arthritis (i.e., spondylarthropathies), Reiter's syndrome (i.e., spondylarthropathies), Crohn's disease, or

ulcerative colitis (see patented claims 14-17, 21, 24, and col., 30, line 19 to col., 31, line 50 in particular). Further, the `527 patent teaches compounds which are capable of inhibiting cytokines production of IL-1, IL-6, IL-8, or TNF (see col., 3, lines 1-25, in particular).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the like patient's conditions such as the psoriatic arthritis, ankylosing spondylitis, or inflammatory bowel diseases such as Crohn's disease and ulcerative collitis taught by the `527 patent with the multiple sclerosis or rheumatoid arthritis in the method of treatment as taught by the `854 patent.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so because the like patient's conditions are mediated by excessive or unregulated cytokine production of IL-1, IL-6, IL-8 or TNF as taught by the `527 patent.

From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

December 6, 2005

Maher Haddad

Maher Haddad, Ph.D.
Patent Examiner
Technology Center 1600